

EXHIBIT Y

Jamie L. Lucia
415 365 6711
jlucia@steptoe.com

Steptoe

One Market Plaza
Spear Tower, Suite 3900
San Francisco, CA 94105
415 365 6700 main
www.steptoec.com

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Via Electronic Mail

Kia Freeman
McCarter & English, LLP
265 Franklin Street
Boston, MA 02110
kfreeman@mccarter.com

Re: ***Indivior, Inc. and Aquestive Therapeutics, Inc. v. BioDelivery Sciences International, Inc., Civil Action No. 5:15-cv-00350-D (E.D.N.C.), and***

Aquestive Therapeutics, Inc. v. BioDelivery Sciences International, Inc., Civil Action No. 5:19-cv-00505-D (E.D.N.C.)

Dear Counsel:

We write in response to BDSI's June 9, 2022, email regarding BDSI's technical documents relating to the accused products in the above-captioned matters. We understand from your response that you refuse to produce any of the [REDACTED], or other similar documents pertaining to the accused products, without regard to relevance or responsiveness.¹ Your unqualified refusal to produce relevant and responsive materials is simply untenable. Under the circumstances, including prior meet and confers on the issue, BDSI's assurances that documents would be promptly produced, followed by three months of silence, BDSI's continued delay in participating in discovery indicates improper gamesmanship.

As you know, Aquestive has propounded numerous discovery requests pertaining to the development, manufacturing, testing, and quality of the accused products, including RFP Nos. 5–18, 46, and 48–49. Aquestive also issued a third-party subpoena to BDSI's manufacturing partner, ARx, on January 11, 2022, seeking similar documents. The core infringement

¹ We also take your letter to indicate that ARx will similarly refuse to produce such documents even if responsive to a revised subpoena to that end.

allegations in these actions are that BDSI's accused products (BUNAVAIL and BELBUCA) and the process for manufacturing them infringe Aquestive's '167 patent. Technical information about the development, manufacture, and testing of those products is, therefore, plainly relevant to the key issues in this case.

We met and conferred regarding these requests on March 1, 2022, with a follow-up call on March 11 and subsequent emails. On our March 1 call, I explained that our requests were directed at records beyond the scope of the batch records disclosed to the FDA, including those that demonstrated the timeline for the decision to develop and development of BUNAVAIL and BELBUCA. We explained that without production of those documents from ARx and BDSI, we were not in a position to identify the full scope of relevant documents at issue. Your colleague Wyley Proctor agreed to confer with your client and with ARx to identify responsive documents based on our meet and confer discussions. Ms. Proctor specifically noted that she had no interest in a drawn-out dispute on this issue and would "at least begin the fight if there's going to be a fight."

In reliance on Ms. Proctor's representations, we withdrew our subpoena to ARx without prejudice to our right to issue another subpoena. It was surprising and disappointing, then, that far from identifying and producing responsive documents or even bringing any dispute to a prompt head, you sat silent for three months only to reveal that neither you nor ARx would produce *anything* on point.

Your substantive objections also do not justify your refusal to produce responsive documents.

First, you have misstated Aquestive's position. Aquestive has never insisted on the production of "all of ARx's [REDACTED]"—although it would be fully within its rights to do so. Rather, as my March 16 email indicated, there are dozens of such documents cited throughout the batch records that you have produced, but it is "very difficult, if not impossible, for Aquestive to determine the full scope and relevancy of these various technical documents," which are not described anywhere in records available us. As I stated then, "it is BDSI's burden to identify, collect, and produce the relevant documents responsive to Aquestive's requests." Needless to say, your bare assertion that producing all such documents would be "unduly burdensome" does not absolve BDSI of its discovery obligations.²

Second, the allegation that the documents we've identified "are not routinely provided to the FDA" is irrelevant. Even if true, it is of no moment that the FDA does not consider such documents as part of its administrative inquiries about the safety and efficacy of the accused products. This is a patent-infringement case in US district court. Aquestive is entitled to discovery into documents that are relevant to its claims and BDSI's defenses.

² Nor would it absolve ARx of an obligation to produce documents responsive to a subpoena.

BDSI's and ARx's various operating procedures regarding the development, formulation, manufacture, and testing of BUNAVAIL and BELBUCA appear squarely on point with the issues in this case, which concern the particularities of that very process. Your description of a single example that pertains to "[REDACTED]" does not demonstrate otherwise, particularly given that this example may actually relate directly to the process conditions for manufacturing the accused products, rendering the example well within the bounds of relevancy. If anything, it tacitly acknowledges that many such records *are* relevant to the issues in this case.³

Finally, your June 9 email entirely failed to address our inquiry regarding "whether there are other similar documents in BDSI's possession, custody, or control that are responsive to Aquestive's requests." As we discussed on our March 1 call, we expect that BDSI would have documents such as emails, lab notebooks, presentations, or minutes of strategy sessions that discuss the development process as well as the process for evaluating which products to pursue. Indeed, Ms. Proctor represented during the meet and confer process that BDSI had identified its own source of documents from which she believed many of these requested technical documents would be produced. Moreover, as I noted in my March 16 email, BDSI's NDA documents refer to various studies and trials, such as those relating to parameter optimization and/or multi-variable design of experiments relating to the manufacturing processes for the accused products. Those do not appear to have been produced, and we take your silence on this point as a refusal to produce them. In fact, BDSI has not made any document production since January 23, 2022, and apparently does not intend to produce anything else.⁴ Given this refusal to participate in the discovery process, it appears that we are at an impasse.

Sincerely,



Jamie Lucia

³ Your note that some unspecified cited documents "do not exist" is simply unhelpful. It strains credulity that BDSI's batch records would cite a document that doesn't exist. Even so, that does not excuse your refusal to produce relevant documents.

⁴ In addition to BDSI's refusal to produce the specific documents discussed in this letter, BDSI has also failed to produce documents in response to most of the document requests Aquestive issued to BDSI. Although Aquestive previously raised those issues in written correspondence, BDSI has not produced documents in the requested categories. *See, e.g.*, correspondence from D. Gelwicks dated February 2, 2022, and February 19, 2022.